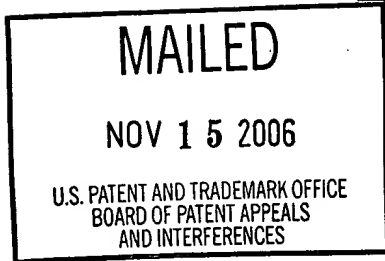


The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHAEL S.H. CHU and YEM CHIN



Appeal No. 2006-0769
Application No. 09/430,050

ON BRIEF

Before FRANKFORT, CRAWFORD and HORNER, Administrative Patent Judges.

FRANKFORT, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1 through 9, 11 through 15 and 21, all of the claims remaining in the application. Claims 10, 16 through 20 and 22 through 31 have been cancelled.

Appellants' invention is directed to a breakaway valve for restricting fluid flow from a peel-away sheath extending from a patient's body. Figures 1 and 2 of the application show one

embodiment of such a valve (20) and an introducer sheath assembly wherein the valve (20) is sealingly attached to a peel-away introducer sheath (54). Alternative embodiments are seen in Figures 2A, 3, 4 and 5 of the drawings. In each instance appellants' breakaway valve includes a compressible valve sleeve (e.g., 24 of Figs. 1-2) carried within a valve body (e.g., 22) having movable valve body members (e.g., 36, 38) and a pinch member (e.g., 40) for compressing the flexible valve sleeve so as to restrict or prevent fluid backflow through the constricted valve sleeve in the closed position of the valve body members, and allow for passage of an inserted catheter while in the open position. (Specification, page 3). Independent claims 1, 3, 12 and 15 are representative of the subject matter on appeal and a copy of those claims can be found in the Appendix attached to appellants' brief.

The sole prior art reference of record relied upon by the examiner in rejecting the appealed claims is:

Heck	6,083,207	Jul. 4, 2000
		(filed Dec. 8, 1998)

Claims 1 through 9, 11 through 15 and 21 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Heck.

Rather than attempt to reiterate the examiner's commentary with respect to the above-noted § 102 rejection and the conflicting viewpoints advanced by appellants and the examiner regarding that rejection, we make reference to the examiner's answer (mailed August 1, 2005) for the reasoning in support of the rejection, and to appellants' brief (filed August 27, 2004) and reply brief (filed September 30, 2005) for the arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to appellants' specification and claims¹, to the

¹ During any further prosecution of the application the examiner should consider whether a rejection of claims 4, 5 and 6 under 35 U.S.C. § 112, second paragraph, and of the claims which depend therefrom, would be appropriate. Claim 3 defines a breakaway valve comprising "means for reversibly restricting fluid flow... wherein said means for reversibly restricting fluid flow includes a compressible valve sleeve and means for compressing said valve sleeve..." Claim 4 depends from claim 3 and adds recitations concerning open and closed positions for said means for reversibly restricting fluid flow. Claim 4 also sets forth the limitation that "said means for admitting said catheter distal end includes..." The problem is that claim 3 does not appear to set forth a "means for admitting said catheter distal end." Thus, there is no proper antecedent basis for "said means for admitting said catheter distal end" currently set forth in claim 4. Claim 5 depends from claim 4 and adds the requirement that the means for reversibly restricting fluid flow
(continued...)

applied prior art Heck patent, and to the respective positions articulated by appellants and the examiner. As a consequence of our review, we have made the determination that the examiner's § 102(e) rejection of claims 1 through 9, 11 through 15 and 21 will not be sustained. Our reasons follow.

Suffice to say that we agree with appellants' assessment of the teachings of Heck. Contrary to the examiner's overly strained view of this patent, the partitioned hemostasis valve system therein does not include "a compressible valve sleeve" (emphasis added) like that of appellants' claims on appeal, or a "means for compressing said valve sleeve for restricting any fluid flow from said peel-away sheath lumen through said valve and valve sleeve lumen," as set forth in claim 1 and the other claims on appeal in varying language. The examiner's positions that the catheter passing through the hemostasis valve of Heck is readable as

¹(...continued)
includes "a flexible, constrictable tube having a lumen therethrough." It is unclear whether the flexible, constrictable tube of claim 5 is in addition to or the same as the "compressible valve sleeve" already set forth in claim 3. In a similar fashion, it is unclear how the "means for pinching said flexible tube..." of dependent claim 6 differs from the "means for compressing said valve sleeve" already set forth in independent claim 3.

appellants' "compressible valve sleeve," and that the neck opening (52) and lips (56) of the valve sections (38) and (40) in Heck would inherently compress a catheter passing through the hemostasis valve to restrict the amount of blood lost during a medical procedure, are untenable.

In the first place, one of ordinary skill in the art would not view the catheter, which may be one of several possible medical devices introduced through the partitioned hemostasis valve of Heck, as being part of the valve. Even more importantly, there is absolutely no basis on which to conclude that the hemostasis valve sections (38) and (40) of Heck are of such character and structure that they would of necessity inevitably compress a catheter passing through the hemostasis valve to restrict any fluid flow from the peel-away sheath lumen through the valve and valve sleeve lumen, as generally set forth in the claims on appeal. The preponderance of the evidence of record establishes that the partitioned hemostasis valve of Heck does not seal by compressing a device, such as a catheter, that is passed through the body of the valve, but instead has valve sections (38, 40) formed from a conventional hemostasis valve material, such as a pliant, resilient rubber, such as silicon rubber, latex rubber, or a foamed rubber (col. 5, lines 53-59) that

is easily deformed or compressed by a device (e.g., catheter) passing through the valve sections, and wherein the valve sections are sufficiently pliant to seal around the external surface of the device and against each other to prevent or restrict flow of fluids from the peel-away sheath lumen through the valve.

As urged by appellants in their brief and reply brief, while it is possible that a catheter or other medical device may be capable of being compressed to some degree, there is absolutely no teaching or suggestion in Heck that the disclosed valve therein has a structure that would or could actually compress a catheter to the degree that the fluid flow through it was substantially restricted, as required in the present case. Indeed, such compression of the catheter would appear to be contrary to the teachings of Heck. See, e.g., column 2, lines 14-31, where it is noted, in the Background section, that a physician might squeeze or pinch the exposed end of a sheath or catheter between his thumb and forefinger to restrict the flow of blood out of the sheath while a pacemaker lead is being introduced, but that such action can deform or even break the sheath, making lead insertion more difficult and increasing the likelihood of damaging the lead as it passes through the sheath. We

also make note of appellants' arguments found on pages 15-18 of the brief and pages 4-12 of the reply brief, which we find persuasive.

In the final analysis, we find that the examiner's conclusion that the openings (52) and lips (56) of Heck's partitioned hemostasis valve members (38, 40) constitute "means for compressing said valve sleeve" (claims 1 and 3), or "a pinch member for pinching said flexible valve sleeve..." (claim 12), so that said flow through said sleeve is "substantially restricted in said closed position" (claim 15), is based entirely on speculation and conjecture.

REVERSED

MURRIEL E. CRAWFORD
Administrative Patent Judge

BOARD OF PATENT
APPEALS
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Appeal No. 2006-0769
Application No. 09/430,050

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